SECTION III.

PRE-510(K) SUMMARY

SUBMITTER: **Bone Support AB**
Ideon Science Park
Ole Romesrv 12
SE-223 Lund Sweden

DATE PREPARED: **September 21st, 2005**

TRADE NAME: **Bone Support AB Cerament™ -**

CLASSIFICATION NAME: **Filler, Bone Void MQV**
Class II Special Controls per
21 CFR 8883045

PREDICATE DEVICES:

510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
K024336	1	MIIG II ™	1	Wright Medical Technology
K010532	2	Osteoset BVF Kit	2	Wright Medical Technology
K022622	3	Cem-Ostetic™	3	Berkley Advanced Biomaterials
K023862	4	Norian® XR	4	Synthes Inc.
K033722	5	ApaPore®	5	Apa Tech Limited
K961511	6	Hapset	6	Lifecore Biomedical

Device Description:

Cerament™ is an injectable bone mineral substitute material intended for stabilization of fractured osteoporotic bone void. The material consists of a powder and a liquid component. The major constituents of the powder component are calcium sulphate hemihydrate and hydroxyl apatite and the liquid component is the radio-contrast agent Iohexol. Mixing of the powder and liquid components results in a viscous mixture suitable for percutaneous injection into the fractured bone void. During resorption of the calcium sulfate dihydrate, the hydroxy apatite remains intact providing osteoconductive support for the in-growth of new bone, which gradually replaces the resorbed calcium sulfate dihydrate.

The bone mineral substitute material is injected into the bone void in a percutaneous procedure with the use of an accompanying injection device. Prior to injection, the powder and liquid components of the substitute material are mixed in a mixing container. The substitute material is injected into the bone void during careful radiographic inspection until the bone void is filled as judged from the radiographic image.

Intended Use:

Bone Support AB Cerament™ - Indications:
Cerament™ is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Cerament™ is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone. Cerament™ provides a bone void filler that resorbs and is replaced by bone during the healing process.
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Technological Characteristics and Substantial Equivalence

Cerament™ is composed of a calcium salt and hydroxyapatite equivalent to that contained in a number of the predicate devices and to that in routine clinical use. The technologies employed in Cerament™ and in its predicate devices is therefore substantially equivalent. Cerament™ is presented in the same manner as its predicate devices. Its indications, contraindications, risks and potential adverse events are the same and thus substantial equivalence is claimed for this device.

Testing

Extensive in vitro and animal testing has shown Cerament™ to meet the requirements of all relevant standards for Calcium Salt Bone Void Fillers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Bone Support AB
c/o Jefferey R. Shideman, Ph.D.
President
International Medical Products Corporation
7307 Glouchester Drive
Edina, Minnesota 55435

Re: K051951
Trade/Device Name: Cerament Bone™ Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: July 8, 2005
Received: July 22, 2005

Dear Dr. Shideman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051951

Device Name: Cerament Bone™ Void Filler

Indications for Use:

Cerament™ is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. Cerament™ is indicated to be injected into bony voids or gaps in the skeletal system, i.e. extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone. Cerament™ provides a bone void filler that resorbs and is replaced by bone during the healing process

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051951